Docket No.

281387US0PCT

#### IN THE U PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Fabrizio SAMARITANI, et al.

SERIAL NO: 10/561,529

GAU:

FILED:

December 20, 2005

**EXAMINER:** 

FOR:

FREEZE-DRIED FSH/LH FORMULATIONS

### INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

#### REFERENCES

- The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

#### RELATED CASES

- Attached is a list of applicant's pending application(s), published application(s) or issued patent(s) which may be related to the present application. In accordance with the waiver of 37 CFR 1.98 dated September 21, 2004, copies of the cited pending applications are not provided. Cited published and/or issued patents, if any, are listed on the attached PTO form 1449.
- A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

### **CERTIFICATION**

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- □ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

#### **DEPOSIT ACCOUNT**

Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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		OTHER RE	FERENCES (	Including Author, Title, Da	ite, Pertinent	Pages, et	c.)	•		•
	AD	BURGUES et al. "Subcutaneous self-administration of highly purified follicle stimulating hormone and human chorionic gonadotrophin for the treatment of male hypogonadotropic hypogonadism", Human Reproduction, vol. 12, no. 5, pages 980-986								
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	AF	KEUTMANN et al. "Structure of Human Luteinizing Hormone Beta Subunit: Evidence for a Related Carboxyl-Terminal Sequence Among Certain Peptide Hormones", Biochemical and Biophysical Research Communications, vol. 90, no. 3, pages 842-848 1979								
	AG	TALMADGE et al. "Evolution of the genes for the beta subunits of human chorionic gonadotropin and luteinizing hormone", Nature, vol. 307, pages 37-40  1984								
	АН	FIDDES et al. "Structure, Expression, and Evolution of the Genes for the Human Glycoprotein Hormones", Recent Progress in Hormone Research, vol. 40, pages 43-78  1984								
	ΑI	REICHERT et al. "Dissociation of Human Follicle-stimulating Hormone", Journal of Biological Chemistry, vol. 250, no. 8, pages 3034-3040 1975								
	AJ	KLEIN et al. "Pharmacokinetics and pharmacodynamics of single-chain recombinant human follicle-stimulating hormone containing the human chorionic gonadotropin carboxyterminal peptide in the rhesus monkey", Fertility and Sterility, vol. 77, no. 6, pages 1248—1255 2002								
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	AQ	KUMAR et al. "Cloning of the mouse gonadotropin beta-subunit-encoding genes, II. Structure of the luteinizing hormone beta-subunit-encoding genes", Gene, vol. 166, pages 335-336  1995  Additional References sheet(s) attached						tached		
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	AR	KUMAR et al. "Cloning of the mouse hormone beta-subunit-encoding gene 1995	gonadotropin beta-subunit-encoding genes e, Gene, vol. 166, pages 333-334	, I. Structure of the follicle-stimulating		
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U.S. PCT Application Serial No: 10/561,529

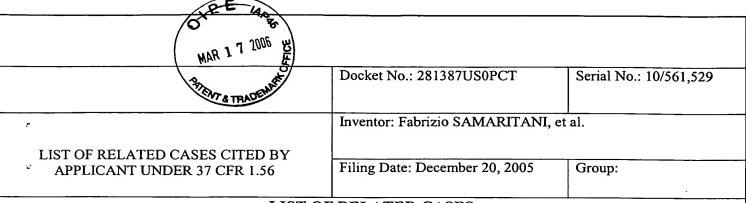
Filed: December 20, 2005 Fabrizio SAMARITANI, et al.

Docket No. 281387US0PCT



## STATEMENT OF RELEVANCY

- 1) References AA-AC have been cited in the International Search Report. A copy of these references is being submitted herewith.
- 2) References have been cited in the corresponding Search Report. A copy of these references is being submitted herewith.
- 3) References AD-AT are discussed in the specification. A copy of these references is being submitted herewith.
- 4) References are additional prior art known to Applicant. A copy of these references is being submitted herewith.



# LIST OF RELATED CASES

Examiner <u>Initial</u>	Docket No.	Serial or <u>Patent</u> <u>Number</u>	Filing or Issue Date	Patent App. <u>Publication No.</u>	Inventor or Applicant
	281387US0PCT*	10/561,529	12/20/05		SAMARITANI, et al.
	278292US0PCT	10/551,840	10/03/05		SAMARITANI, et al.

Examiner

Date Considered